

PATENT
Attorney Docket No. CPC-006CN2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Biondi *et al.*
SERIAL NO.: Not yet assigned GROUP NO.: Not yet assigned
FILING DATE: Herewith EXAMINER: Not yet assigned
TITLE: A System for Automatically Weaning a Patient from a Ventilator, and
Method Thereof

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. In accordance with the U.S. Patent Office's partial waiver of the requirement under 37 C.F.R. 1.98(a)(2)(i), paper copies of references A1-A110 are not enclosed. Per 37 C.F.R. 1.98(d), references B1-B14 and C1-C21 were previously submitted to, or cited by, the U.S. Patent Office in U.S. Patent Applications Nos. 08/569,919, 09/045,461, 09/660,820, 09/767,173, and/or 10/260,796, which are relied upon in the present case for an earlier effective filing date under 35 U.S.C. 120, and, therefore, paper copies of these references are not enclosed. Should the Examiner require paper copies of some or all of these references, the Undersigned may be contacted at the telephone number listed below.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first** Office

action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. 1.114; or

- (2) **after the period defined in (1) but before the mailing date of a final action or a notice of allowance under 37 C.F.R. 1.311, and**
 - the requisite Statement is below, OR**
 - the requisite fee under 37 C.F.R. 1.17(p), namely \$180.00, is included herein, or**
- (3) **after the mailing date of a final action or notice of allowance but before the payment of the issue fee, AND**
 - the requisite Statement is below, AND**
 - the requisite petition fee under 37 C.F.R. 1.17(p), namely \$180.00 is included herein.**

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

- 1. **Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or**
- 2. **No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual designated in 37 C.F.R. 1.56(c) more than three months** prior to the filing of the Information Disclosure Statement.**

Respectfully submitted,


Ronda P. Moore

Ronda P. Moore
Attorney for the Applicants
Testa, Hurwitz, & Thibeault, LLP
High Street Tower
125 High Street
Boston, Massachusetts 02110

Date: November 17, 2003
Reg. No. 44,244

Tel. No.: (617) 248-7044
Fax No.: (617) 248-7100

2712461_1

FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT		ATTY DOCKET NO.: CPC-006CN2 APPLICANTS: Biondi <i>et al.</i> SERIAL NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned
---	--	--

U.S. PATENT DOCUMENTS

EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
A1	RE. 35,295	07/16/96	Estes et al.			08/24/94
A2	3,212,496	10/19/65	Richard J. Preston			08/21/62
A3	3,741,208	06/26/73	Jonsson, et al.			02/23/71
A4	3,835,845	9/17/74	Charles E. Maher			10/24/72
A5	3,923,055	12/2/75	Konrad Hammacher			11/15/74
A6	3,961,627	06/08/76	Ernst et al.			09/03/74
A7	3,972,327	8/3/76	Ernst et al.			11/07/74
A8	3,976,064	08/24/76	Wood et al.			03/11/75
A9	4,016,871	4/12/77	Peter Schiff			03/06/75
A10	4,036,221	7/19/77	Hillsman et al.			04/02/75
A11	4,050,458	09/27/77	Friend			01/26/76
A12	4,141,356	02/27/79	Smargiassi			11/18/77
A13	4,163,450	8/7/79	Kirk et al.			01/27/77
A14	4,176,663	12/04/79	Hewlett			10/04/77
A15	4,204,524	5/27/80	Martin et al.			11/07/77
A16	4,256,100	03/17/87	Levy et al.			02/12/79
A17	4,281,651	08/04/81	Cox			07/30/79
A18	4,323,064	4/6/82	Hoenig et al.			06/01/79
A19	4,340,044	7/20/82	Levy et al.			03/20/80
A20	4,413,632	11/8/83	Schlessinger et al.			10/09/79
A21	4,417,573	11/29/83	De Vries			07/02/81
A22	4,424,806	1/10/84	Newman et al.			03/12/81
A23	4,444,201	04/24/84	Ayao Itoh			08/19/81
A24	4,448,192	5/15/84	Stawitcke et al.			03/05/82
A25	4,456,008	01/26/84	Clawson et al.			09/13/82

EXAMINER	DATE CONSIDERED
-----------------	------------------------

FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT		ATTY DOCKET NO.: CPC-006CN2 APPLICANTS: Biondi <i>et al.</i> SERIAL NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned
---	--	--

U.S. PATENT DOCUMENTS

EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A26	4,459,982	07/17/84	Fry		09/13/82
	A27	4,546,770	10/15/85	Schlessinger et al.		03/04/83
	A28	4,637,385	01/20/87	Rusz		01/13/86
	A29	4,676,232	06/30/87	Olsson et al.		09/16/86
	A30	4,838,257	6/13/89	Guy M. Hatch		07/17/87
	A31	4,840,167	06/20/89	Olsson et al.		04/15/87
	A32	4,877,023	10/31/89	Zalkin		02/25/88
	A33	4,917,080	04/17/90	Bayerlein		05/19/89
	A34	4,928,674	5/29/90	Halperin et al.		11/21/88
	A35	4,984,158	01/08/91	Hillsman		10/14/88
	A36	4,986,268	1/22/91	Fleur T. Tehrani		08/18/88
	A37	4,990,894	02/05/91	Loescher et al.		11/01/89
	A38	5,020,516	6/4/91	Biondi et al.		03/31/88
	A39	5,040,529	08/20/91	Zalkin		04/14/89
	A40	5,072,737	12/17/91	Peter Goulding		04/12/89
	A41	5,092,326	03/03/92	Winn et al.		11/19/87
	A42	5,097,424	03/17/92	Ginevri et al.		03/18/91
	A43	5,103,814	04/14/92	Maher		08/24/89
	A44	5,107,831	4/28/92	Halpern et al.		06/06/91
	A45	5,129,390	7/14/92	Chopin et al.		12/13/88
	A46	5,161,525	11/10/92	Kimm et al.		05/11/90
	A47	5,183,038	02/02/93	Hoffman et al.		11/04/91
	A48	5,188,098	2/23/93	Hoffman et al.		11/04/91
	A49	5,271,389	12/21/93	Isaza et al.		02/12/92
	A50	5,299,568	04/05/94	Forare et al.		01/11/93

EXAMINER

DATE CONSIDERED

FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT				ATTY DOCKET NO.: CPC-006CN2 APPLICANTS: Biondi <i>et al.</i> SERIAL NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned			
U.S. PATENT DOCUMENTS							
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A51	5,303,698	04/19/94	Tobia et al.			08/27/91
	A52	5,303,699	04/19/94	Bonassa et al.			11/18/91
	A53	5,309,919	05/10/94	Snell et al.			03/02/92
	A54	5,316,009	05/31/94	Yamada			07/01/92
	A55	5,319,540	06/07/94	Isaza et al.			09/07/93
	A56	5,323,772	06/28/94	Linden et al.			06/01/92
	A57	5,331,995	7/26/94	Westfall et al.			07/17/92
	A58	5,373,842	12/20/94	Olsson et al.			12/18/91
	A59	5,377,671	01/03/95	Biondi et al.			09/16/91
	A60	5,383,449	01/24/95	Forare et al.			09/28/93
	A61	5,390,666	02/21/95	Kimm et al.			12/03/93
	A62	5,400,777	03/28/95	Olsson et al.			04/15/93
	A63	5,402,796	04/04/95	Packer et al.			09/19/91
	A64	5,419,314	05/30/95	Christopher			12/13/93
	A65	5,429,123	07/04/95	Shaffer et al.			12/15/93
	A66	5,433,193	07/18/95	Sanders et al.			09/18/92
	A67	5,438,980	08/08/95	Phillips			01/12/93
	A68	5,515,844	05/14/96	Christopher			05/26/95
	A69	5,520,192	05/28/96	Kitney et al.			11/21/94
	A70	5,535,738	07/16/96	Estes et al.			06/03/94
	A71	5,540,233	07/30/96	Larsson et al.			10/24/94
	A72	5,549,106	08/27/96	Gruenke et al.			07/21/93
	A73	5,551,418	09/03/96	Estes et al.			08/23/93
	A74	5,558,086	09/24/96	Smith et al.			11/23/94
	A75	5,596,984	01/28/97	O'Mahony et al.			09/12/94
EXAMINER				DATE CONSIDERED			

FORM PTO - 1449		ATTY DOCKET NO.: CPC-006CN2					
INFORMATION DISCLOSURE STATEMENT		APPLICANTS: Biondi <i>et al.</i>					
		SERIAL NO.: Not yet assigned					
		FILING DATE: Herewith GROUP: Not yet assigned					

U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A76	5,598,838	02/04/97	Servidio et al.			04/07/95
	A77	5,630,411	05/20/97	Holscher			09/18/95
	A78	5,632,270	05/27/97	O'Mahony et al.			09/12/94
	A79	5,660,171	08/26/97	Kimm et al.			08/21/96
	A80	5,664,563	09/09/97	Schroeder et al.			12/9/94
	A81	5,692,497	12/02/97	Schnitzer et al.			05/16/96
	A82	5,740,796	04/21/98	Skog			11/06/96
	A83	5,743,253	04/28/98	Castor et al.			01/19/96
	A84	5,806,513	09/15/98	Tham et al.			10/11/96
	A85	5,862,802	01/26/99	Bird			11/23/92
	A86	5,868,133	02/09/99	DeVries et al.			02/03/97
	A87	5,875,777	03/02/99	Eriksson			04/24/97
	A88	5,878,744	03/09/99	Pfeiffer			07/22/97
	A89	5,881,723	03/16/99	Wallace et al.			03/14/97
	A90	5,915,380	06/29/99	Wallace et al.			03/14/97
	A91	5,915,381	06/29/99	Nord			12/02/96
	A92	5,918,597	07/06/99	Jones et al.			01/15/98
	A93	5,927,274	07/27/99	Servidio et al.			02/03/97
	A94	5,931,159	08/03/99	Suzuki et al.			06/10/97
	A95	5,931,160	08/03/99	Gilmore et al.			12/08/95
	A96	5,931,162	08/03/99	Christian			06/03/97
	A97	5,937,853	08/17/99	Ström			11/06/96
	A98	5,957,130	09/28/99	Krahbichler et al.			08/25/97
	A99	6,000,396	12/14/99	Melker et al.			08/17/95
	A100	6,015,388	01/18/00	Sackner et al.			03/17/98

EXAMINER	DATE CONSIDERED
-----------------	------------------------

FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT		ATTY DOCKET NO.: CPC-006CN2 APPLICANTS: Biondi <i>et al.</i> SERIAL NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned
---	--	--

U.S. PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A101	6,024,089	02/15/00	Wallace et al.			03/14/97
	A102	6,029,664	02/29/00	Zdrojkowski et al.			03/25/97
	A103	6,076,523	06/20/00	Jones et al.			01/15/98
	A104	6,095,139	08/01/00	Psaros			09/08/98
	A105	6,148,814	11/21/00	Clemmer et al.			02/08/96
	A106	6,158,432	12/12/00	Biondi			03/20/98
	A107	6,158,433	12/12/00	Ong et al.			11/06/98
	A108	6,182,667	02/06/01	Hanks et al.			04/02/99
	A109	6,305,372	10/23/01	Servidio			06/24/99
	A110	6,463,930	10/15/02	Biondi et al.			01/22/01

FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B1	2 348 582	11/27/73	DE					
	B2	0 182 722	05/28/86	EP					
	B3	0 342 443	05/19/88	EP					
	B4	0 274 996	07/20/88	EP					
	B5	0 993 841 A1	04/19/00	EP					
	B6	2,729,084	12/13/95	FR					
	B7	8 801 322		NL					
	B8	2 162 430A	02/05/86	UK					
	B9	92/11054	07/09/92	WO					
	B10	92/11054A	07/09/92	WO					
	B11	96/17641A	06/13/96	WO					
	B12	97/20592A	06/12/97	WO					

EXAMINER**DATE CONSIDERED**

FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT		ATTY DOCKET NO.: CPC-006CN2 APPLICANTS: Biondi <i>et al.</i> SERIAL NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned							
---	--	--	--	--	--	--	--	--	--

FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B13	99/47200A	09/23/99	WO					
	B14	00/45880A	08/10/00	WO					

OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C1 Adult Star Ventilator "Adult Star Ventilator Operating Instructions" <u>Adult Star Ventilator</u>	
	C2 Bear Medical Systems, Inc. "Bear 5 Medical Ventilator Instruction Manual" <u>Bear Medical Systems, Inc.</u> (1985)	
	C3 Brochard et al., "Comparison of Three Methods of Gradual Withdrawal from Ventilatory Support during Weaning from Mechanical Ventilation," <u>Am. J. Resp. Crit. Care Med.</u> (1994), Vol. 150, pgs. 896-903.	
	C4 Dries, "Weaning from Mechanical Ventilation," <u>Journal of Trauma: Injury, Infection, and Crit. Care</u> , (1997), Vol. 43, No. 2, pgs. 372-384.	
	C5 East, T.D., "The Ventilators of the 1990's", <u>Respiratory Care</u> 35: 232-240 (1990).	
	C6 Esteban et al., "A Comparison of Four Methods of Weaning Patients from Mechanical Ventilation," <u>N.E. Journal of Med.</u> , (1995) Vol. 332, No. 6, pgs. 345-350.	
	C7 Fontes et al., "Early Extubation Following Cardiac Surgery: Is the Clock Running out on the Elderly?," <u>Cardiopulmonary Corp.</u> , Abstract: 1997 American Society for Anesthesiology (1 pg.).	
	C8 Fontes, et al., "Is Computer-Driven Weaning from Mechanical Ventilation Superior to Clinician-Directed Weaning Following Cardiac Surgery?," <u>Cardiopulmonary Corp.</u> , Abstract: 1997 American Society of Cardiovascular Anesthesiology (1 pg.).	
	C9 Fontes et al., "Does Automated Weaning from Mechanical Ventilation Following Cardiac Surgery Increase the Incidence of Adverse Cardiopulmonary Events?," <u>Cardiopulmonary Corp.</u> , Abstract: 1998 Society of Cardiovascular Anesthesiology (1 pg.).	
	C10 Hamilton Medical "Veolar Operator's Manual" <u>Hamilton Medical</u> (July 1988)	
	C11 Hitchin, J., "Computerized Pulmonary Diagnostics for Infants and Children" <u>Biomedical Business International</u> Section 7: 1-3/24 (May 23, 1990)	
	C12 International Search Report for PCT/US02/01716.	
	C13 Kollef et al., "A randomized, controlled trial of protocol-directed versus physician-directed weaning from mechanical ventilation." <u>Crit. Care Med.</u> (1997) Vol. 25, No. 4, pgs. 567-574.	
EXAMINER		DATE CONSIDERED

FORM PTO - 1449 INFORMATION DISCLOSURE STATEMENT		ATTY DOCKET NO.: CPC-006CN2 APPLICANTS: Biondi <i>et al.</i> SERIAL NO.: Not yet assigned FILING DATE: Herewith GROUP: Not yet assigned
OTHER ART, JOURNAL ARTICLES, ETC.		
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
C14	Noack, G., M.D., "Ventilatory Treatment of Neonates and Infants" <u>Siemens</u> (April 1993)	
C15	Puritan Bennett "Puritan Bennett 7200 Series Ventilator, Options, and Accessories - Operation's Manual - Part Number 22300A" <u>Marketing Communications Department - Puritan-Bennett Corporation</u> 1-6/9 (September 1990)	
C16	Sanborn, W.G., "Ventilation in the Information Age", presented at the Product Opportunities in Critical Care Medicine, Puritan-Bennett Corporation, Carlsbad, CA., May 18, 1989.	
C17	Scalise et al., "Comparison of the Average Operating Airway Pressures of the Puritan-Bennett 7200 Ventilator and the Venturi Ventilator in Patients Undergoing Weaning from Prolonged Mechanical Ventilators," Cardiopulmonary Corp., Abstract: 2000 Society for Critical Care Medicine (1 pg.).	
C18	Scalise et al., "Comparison of Two Weaning Strategies in Patients Undergoing Prolonged Mechanical Ventilation," Cardiopulmonary Corp., Abstract: 2000 American College of Chest Physicians (1 pg.).	
C19	Siemens "Servo Ventilator 300 Service Manual - Preliminary" <u>Siemens</u> (1991)	
C20	Siemens "Servo Ventilator 900C Operating Manual" <u>Siemens</u>	
C21	Wallis et al., "Mechanical Heart-lung interaction with positive end-expiratory pressure", J. Appl. Physiol; Respirat. Environ. Exercise Physiol. 54: 1039-1047 (1983).	
EXAMINER	DATE CONSIDERED	

2643244